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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/972,799	10/05/2001	Mohler Hanns	9261-005	5224
20583	7590	06/28/2004	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			LANDSMAN, ROBERT S	
		ART UNIT	PAPER NUMBER	
		1647		

DATE MAILED: 06/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/972,799	HANNS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 20 May 2004.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 2-18 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1, 19-21 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***1. Formal Matters***

- A. Claims 1-21 are pending in the application. Claims 2-18 have been withdrawn as being drawn to a non-elected invention. Therefore, claims 1 and 19-21 are the subject of this Office Action.
- B. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

### ***2. Title***

- A. The objection to the title has been withdrawn in view of Applicants' amendment which more clearly points out the claimed subject matter.

### ***3. Claim Rejections - 35 USC § 112, first paragraph - enablement***

- A. All rejections under 35 USC 112, first paragraph, have been withdrawn in view of Applicants' amendment to remove the term "binds" as well as their arguments. Applicants have pointed out exactly where in the specification they have support (i.e. enablement) for the scope of the claims.

### ***4. Claim Rejections - 35 USC § 112, first paragraph – written description***

- A. All rejections under 35 USC 112, first paragraph, have been withdrawn in view of Applicants' amendment to remove the term "binds" as well as their arguments. Applicants have pointed out exactly where in the specification they have support (i.e. enablement) for the scope of the claims.

### ***5. Claim Rejections - 35 USC § 112, first paragraph – new matter***

- A. Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim recites "to the same degree." However, there is no support for this limitation in the specification. This is a new matter rejection. If Applicants believe this is not new matter, they are required to point out exactly where in the specification there is support for this limitation.

**6. Claim Rejections - 35 USC § 112, second paragraph**

A. Claims 19-21 recite the limitation "the  $\alpha$ 3-GABA<sub>A</sub> or  $\alpha$ 5-GABA<sub>A</sub>." There is insufficient antecedent basis for this limitation in the claim. It is suggested that the claims be amended to recite, for example, "The method of claim 1 further comprising  $\alpha$ 3-GABA<sub>A</sub> or  $\alpha$ 5-GABA<sub>A</sub>, and wherein the candidate molecule..."

**7. Claim Rejections - 35 USC § 102**

A. Claims 1 and 19-21 remain rejected under 35 USC 102 as being anticipated by Ladduwahetty et al. for the reasons already of record on page 5 of the Office Action dated 11/20/03. Applicants argue that the present claims are drawn to a method of screening and that Ladduwahetty do not teach such a method, nor has such a method been carried out inherently. Applicants argue that Ladduwahetty only teach measuring the Ki values of  $\alpha$ 2,  $\alpha$ 3 and  $\alpha$ 5 GABA receptors and that no experiments were performed for  $\alpha$ 1. Therefore, no comparisons were made between  $\alpha$ 1 and  $\alpha$ 2. Furthermore, Applicants argue that no activity was measured in Ladduwahetty.

These arguments have been considered, but are not deemed persuasive. As discussed previously, Ladduwahetty do teach (column 2, lines 20-24) that GABA receptor agonist which bind more efficiently to the  $\alpha$ 2 and/or  $\alpha$ 3 subunit than to the  $\alpha$ 1 subunit will be effective in the treatment of anxiety. Though Ladduwahetty do not specifically teach a screening method as taught in the present invention, they have anticipated the present invention. Applicants invention is the determination that activation of a ligand to  $\alpha$ 2 as compared to  $\alpha$ 1 will produce an anxiolytic effect with reduced sedation. This concept is taught by Ladduwahetty. The teaching of screening methods is not required in the reference, as it would be immediately envisioned by one of ordinary skill in the art as screening method to identify receptor ligands is routine. Furthermore, the fact that the prior art discusses "agonists" and "antagonists" implies that these ligands have an activity at GABA receptors. Though the reference says "and/or," it still allows for the interpretation of "or," which would read on the present invention. Similarly, claim 1 of the present invention does not rule out the possibility of the  $\alpha$ 3 subunit being involved, as the claim recites a method "comprising." Furthermore, it is brought to Applicants' attention that the claimed methods do not distinguish from the general practice of screening for ligands with a reduced anxiolytic effect since the artisan, in simply screening compounds, would inherently find compounds which selectively bind  $\alpha$ 2 as opposed to  $\alpha$ 1, regardless of whether or not this was their intention.

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B. Claims 1 and 19-21 remain rejected under 35 USC 102 as being anticipated by Rudolph et al. for the reasons already of record on pages 5-6 of the Office Action dated 11/20/03. Applicants argue that the reasons argued above regarding Ladduwahetty hold for Rudolph. These arguments have been considered, but are not deemed persuasive for the reasons stated above regarding Ladduwahetty. The passage for Rudolph can be seen on page 799, first full paragraph.

***8. Claim Rejections - 35 USC § 103***

A. Claims 1 and 19-21 remain rejected under 35 USC 103 as being unpatentable over Ladduwahetty et al. for the reasons already of record on page 6 of the Office Action dated 11/20/03. Applicants provide substantially the same arguments as for the 102 rejection. Applicants major argument in this case is that Ladduwahetty did not know which receptor subunit was responsible for the anxiolytic effect of GABA ligands and that they were merely speculating. However, this argument is also not deemed persuasive for the reasons provided above.

B. Claims 1 and 19-21 remain rejected under 35 USC 103 as being unpatentable over Rudolph et al. for the reasons already of record on pages 6-7 of the Office Action dated 11/20/03. Applicants provide substantially the same arguments as for the 102 rejection. Applicants major argument in this case is that Ladduwahetty did not know which receptor subunit was responsible for the anxiolytic effect of GABA ligands and that they were merely speculating. However, this argument is also not deemed persuasive for the reasons provided above.

***9. Conclusion***

A. No claim is allowable.

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***Advisory information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (571) 272-0887.

Official papers filed by fax should be directed to (703) 872-9306. Fax draft or informal communications with the examiner should be directed to (571) 273-0888.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-0700.

Robert Landsman, Ph.D.

Patent Examiner

Group 1600

June 14, 2004



ROBERT LANDSMAN  
PATENT EXAMINER